Remarks

I. Rejection under 35 U.S.C. § 103

Claims 1-15 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,475,510 to Venkatesh *et. al.* It is the Examiners' position that Venkatesh *et. al.*'510 teaches a fast-dispersible tablet for oral administration containing an active ingredient, a waxy material including mono-, di- or tri- aliphatic esters of glycerol,. preferably glycerol palmitostearate (Precirol®) (col. 5, lines 31-39) and a sweetener and/or a taste-masking agent to reduce bitter tasting ingredients (see col. 3, line 14 - col. 4, line 5) such as the lipoproteins and phospholipids derived from soy lecithin (col. 4, line 10 - col. 5, line 30).

The waxy material is present at a level of from about 1% to about 30%. While the Examiner admits that this range is lower than Applicant's claimed range of about 60% to about 80%, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. It is further argued that suitable or effective amounts of glycerol and/or fatty acid can be determined by one of ordinary skill in the art through the use of routine or manipulative experimentation to obtain optimal results, as these are variable parameters attainable within the art.

Moreover, it is admitted that while Venkatesh *et al.* '510 does not explicitly teach a particle size of less than about 350 µm, it is then noted that the claim language "which can produce a particle size of less than about 350 gm" imparts future-intended use language and thus, does not afford patentable weight to the claims. Moreover, no unexpected results accrue from the instantly claimed particle size. Effective particle sizes can be determined by one of ordinary skill in the art through the routine optimization process. Therefore, Thus, given the teachings of Venkatesh *et al.* '510 delineated above, the instant invention, when taken as a whole, are asserted to be *prima facie* obvious to one of ordinary skill in the art at the time the invention was made. This rejection is also respectfully traversed for the following reasons.

The compositions of the present invention as recited in the newly amended claims comprise from about 15 to about 30% of active ingredient (principle) mixed with from about 50% to about 85% of an acid pH-sensitive release system consisting of glyceryl stearate, glyceryl palmitostearate and mixtures thereof to which a wax and a surfactant is added. Support for the amendments may be found at pages 6 – 10 of the specification. The

pharmaceutical active delivery system is prepared by a spray-cooling method which produces a particle size of less than 350 µm. As stated before, the main advantage of the compositions of the present invention is that the glyceryl stearate and glyceryl palmitostearate used singly or in combination and their amounts not only taste mask the bitter or irritating olefactory characteristics of many bad tasting pharmaceutical actives, in particular strong tasting antibiotics, but also have a suitable pH-sensitivity profile that delays dispersion and release of the active principle only on a delayed basis at acid pH conditions as encountered in the stomach. The claims are now limited to those compositions that afford this release-profile feature the These specific glycerol esters then, serve to delay the release of the active until it passes the olefactory sensory system and enters the stomach. Nothing like this is disclosed in the cited prior art

The use of these glycerol esters together with the small particle size of the pharmaceutical active/glycerol ester component result in the advantage of an effective masking of taste coupled with a lack of the sandy or bitter feeling of the composition normally affiliated with said pharmaceutical active in the mouth.

The Venkatesh *et al.* '510 patent cited by the Examiner as rendering claims 1 -15 obvious under 35 U.S.C § 103 does not teach or suggest the instant claimed particle size of less than 350µ (see currently amended claim 1, and p. 2, ln. 31), nor does it teach the use of glyceryl stearate and glyceryl palmitostearate singly or in combination as taste masking agents. The Examiner has repeated admitted that the Venkatesh *et al.* '510 patent does not teach particle sizes less than 350µ and that suitable taste-masking agents in the intragranular formulation disclosed therein include lipoproteins and phospholipids derived from soy lecithin (col. 5, lines 40-44), not glyceryl stearate and glyceryl palmitostearate, i.e., esters of glycerol. Claim 1 (and hence all the pending claims dependent therefrom) has been amended herein to recite the fact that the claimed taste-masking composition of the present invention exhibits an acid pH-sensitive release profile partially at least, due to the fact that the particles of the present invention are less than 350µ. This small particle size limitation is an important inventive and functional feature of the invention since this removes the sandy or chalky feeling of the composition normally affiliated with said pharmaceutical active in the mouth.

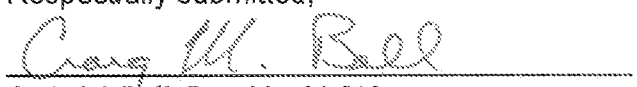
Glycerol esters may be discussed as possible components of the intra-granular

formulation of Venkatesh *et al.* '510 but the use of glyceryl stearate or glyceryl palmitostearate and their mixtures are not discussed or disclosed anywhere therein as being useful as taste masking agents. In fact, the patent only discloses them as being waxy materials (col. 5, ln. 31 – 39) with no real function recited therein. It cannot be said that there is anything evident in the patent that teaches the combination of elements recited in the claims of the present application that are the spray-dried and cooled using a two-fluid nozzle to ensure that the desired particle size is obtained, i.e. a particle size less than 350μ. diameter as described above. The compositions now defined by the claims as amended are totally different from those of Venkatesh *et al.* '510 and therefore, one skilled in the art, knowing that disclosed therein could not reasonably expect how to prepare the acid pH-sensitive release taste masking compositions as disclosed and recited in the claims of the present application. For it is well established that chemistry is a highly empiricle science and one can rarely predict, if ever, how two or more different compounds will react when placed under similar conditions or environments or combined with other compound(s). In re Johnson 747 F. 2nd 1456,1460; 223 U.S.P.Q.1260, (Fed. Cir.1984); In re Papesch 315 F. 2nd 381, 137 U.S.P.Q. 43 (C.C.P.A.1963) Therefore, despite the quasi-similar structures found in the instant claimed compounds and those of the prior art, those of the present claimed invention cannot be considered obvious. Respectfully, the rejection of claims 1,3,7,11-14, 16, 17 and 19 as being unpatentable for obviousness under 35 U.S.C. § 103(a) in view of Venkatesh *et al.* '510 should be withdrawn.

In light of the foregoing amendments to the claims and arguments as to their patentability, it is respectfully asserted that the remaining pending claims recite patentable subject matter that is clearly distinguishable and an advance over the cited prior art. It is further respectfully requested that said rejections of the claims be withdrawn so that they might pass to allowance and issue. Should however, the Examiner still have some remaining issue(s) or concern(s), he is earnestly solicited to contact the undersigned attorney

so that any un-resolved matter might be overcome and resolved.

Respectfully submitted,



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